510(k) Summary
for
DANA 3cc Syringe Insulin Reservoir

SEP - 4 2007

1. SPONSOR

Sooil Development Co., Ltd.
196-1, Dogok-dong, Kangnam-gu
Seoul, 135-270, KOREA

Contact: Soo Bong Choi, CEO

Telephone: (82) 2-3463-0041
Facsimile: (82) 2-3463-7077

Date Prepared: July 9, 2007

2. DEVICE NAME

Proprietary Name: DANA 3cc Syringe Insulin Reservoir
Common/Usual Name: Insulin reservoir
Classification Name: Accessories, infusion pump

3. PREDICATE DEVICES

- SOOIL Development Co., Ltd., DANA Diabecare® (K001604)*
- Spectrx, Inc., SimpleChoice 3.0 ml Reservoir Pro (K051045)
- Applied Diabetes Research, Inc., SureSet 3.0 ml Reservoir (K024056)
- Sterling Medivations, Inc., Simplicity Infusion Reservoir (K013767)
- Medtronic MiniMed, Inc., 3.0 ml Reservoir Model 103/193 (K991936)

*Insulin reservoir accessory included in K001604

4. DEVICE DESCRIPTION

The DANA 3cc Syringe Insulin Reservoir is a sterile, single-use, non-pyrogenic, syringe that is designed for use with all versions of the DANA Diabecare® Insulin pump that have been cleared for marketing in the U.S. (K001604, K022317, and K063126). The syringe reservoir is a 3 ml polypropylene syringe with a 300 unit insulin capacity that is supplied with a 22 gauge, 12.7 mm straight needle. The

reservoir is filled similarly to filling an insulin syringe. Once filled and inspected for entrapped air, the needle is removed and the syringe reservoir is inserted into the DANA Diabecare® Insulin pump. The syringe plunger has grooves cut into the distal end for attachment to the linking screw that connects the syringe reservoir to the gearbox of the DANA Diabecare® Insulin Pump.

The proposed DANA 3cc Syringe Insulin Reservoir is a modification of the insulin reservoir accessory described in K001604, the original 510(k) premarket notification for the DANA Diabecare® Insulin Pump. The modification was limited to a change in the gasket configuration and material. The proposed DANA 3cc Syringe Insulin Reservoir has a ring shape gasket that is manufactured from silicone.

5. INTENDED USE

The DANA 3cc Syringe Insulin Reservoir is an accessory to the DANA Diabecare® Insulin Pumps. The DANA 3cc Syringe Insulin Reservoir is intended for the delivery of insulin from the DANA Diabecare® Insulin Pumps using specified insulin administration sets.

The DANA 3cc Syringe Insulin Reservoir is intended exclusively for use with the DANA Diabecare® Insulin Pumps. The DANA Diabecare® Insulin Pumps are external programmable syringe infusion pumps used for the subcutaneous delivery of insulin for the treatment of diabetes mellitus. The pumps are not intended for use with blood or blood products.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The material components and technological characteristics of the proposed DANA 3cc Syringe Insulin Reservoir and the predicate devices are similar. All of the devices are 3.0 ml piston syringes with a 300 unit insulin capacity. The proposed DANA 3cc Syringe Insulin Reservoir and the predicate devices are supplied sterile and are indicated for single use.

The proposed DANA 3cc Syringe Insulin Reservoir and the predicate devices are indicated for use only with a specified insulin pump. As stated elsewhere, the proposed DANA 3cc Syringe Insulin Reservoir and the predicate insulin reservoir described in K001604 are designed specifically for use with the DANA Diabecare® Insulin Pump. The other predicate reservoirs (SimpleChoice 3.0 ml Reservoir (K051045), Sureset 3.0 ml Reservoir (K024056), Simplicity Infusion Reservoir (K013767), and MiniMed 3.0 ml Reservoir (K991936)) are designed exclusively for use with the Medtronic MiniMed® pumps.

Comparison Chart for Determination of Substantial Equivalence

Item for Comparison	**DANA 3cc Syringe Insulin Reservoir (Proposed)**	**DANA Insulin Reservoir (K001604)**	**Simplicity Infusion Reservoir (K013767)**	**MiniMed 3.0 ml Reservoir (K991936)**
Intended Use	Infusion reservoirs for use to infuse insulin from an external infusion pump			
Insulin Pump	DANA Diabecare® Insulin Pumps	DANA Diabecare® Insulin Pumps	Medtronic MiniMed® Pumps	Medtronic MiniMed® pumps
Technical Specifications	• 3 ml syringe • 300 unit capacity	• 3 ml syringe • 300 unit capacity	• 3 ml syringe • 300 unit capacity	• 3 ml syringe • 300-unit capacity
Sterility Status	• Supplied sterile • Single use	• Supplied sterile • Single use	• Supplied sterile • Single use	• Supplied sterile • Single use

7. PERFORMANCE TESTING

Design verification activities for the DANA 3cc Syringe Insulin Reservoir included biocompatibility testing, evaluation of physical and functional characteristics, and shelf-life testing. The results confirm that the DANA 3cc Syringe Insulin Reservoir is suitable for use as an insulin reservoir for all legally marketed versions of the DANA Diabecare® Insulin Pumps and support the claimed shelf life.

Deleted: a three-year

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sooil Development Company, Limited
C/O Cynthia J.M. Nolte, Ph.D., RAC
Senior Regulatory Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

SEP - 4 2007

Re: K071418
Trade/Device Name: DANA 3cc Syringe Insulin Reservoir
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ
Dated: July 9, 2007
Received: July 10, 2007

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071418

Device Name: DANA 3cc Syringe Insulin Reservoir

Indications for Use:

The DANA 3cc Syringe Insulin Reservoir is an accessory to the DANA Diabecare® Insulin Pumps. The DANA 3cc Syringe Insulin Reservoir is intended for the delivery of insulin from the DANA Diabecare® Insulin Pumps using specified insulin administration sets.

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Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K071418